INFORMATION FOR POTENTIAL PARTICIPANTS

The Finnish Hematology Registry (FHR): Population-based follow-up study on the emergence, incidence, diagnostics, treatments and treatment outcomes of blood disorders and inherited bleeding disorders in Finland

Dear candidate,

We are writing to you to ask if you would like to participate in the study outlined below.

Background of the study

Despite being relatively rare, blood disorders have a significant clinical, scientific, and health-economic impact. Comprehensive and up-to-date information on the emergence, incidence, diagnostic methods, available treatments and prognosis of blood disorders is insufficient in Finland. This makes it difficult to develop treatments and evaluate their quality. Due to the stricter safety requirements for medicinal products, both Finnish and European pharmaceutical authorities have begun to require systematic monitoring of the use of new medicines and medicinal products, such as plasma products. This can only be achieved through a nation-wide registry. The duty to maintain a registry includes the disclosure of the collected data to non-resident registries without identifying information, such as one’s personal identity code or place of residence details.

Together with its subordinate organizations the Hematological Disorders Study and Treatment Group and the Finnish Hemophilia Group, the Finnish Hematology Association (SHY) launched the registry project (the Finnish Hematology Registry, FHR) in 2009. The project objective is to gather comprehensive information on the emergence, incidence, diagnostic methods, treatments, monitoring and prognoses of blood disorders in Finland. This study is a means of gathering information nationwide in a comprehensive register. In the future, FHR will be a key tool in planning the treatment of blood disorders and providing consistent treatment in Finland. It also provides a way to meet challenges relating to the safety and efficacy of medicinal products.

Implementation of the study

Consent is requested for the study from all who have been diagnosed with a disease affecting blood-forming tissues or the lymphatic system, or an inherited or acquired coagulation disorder. The key is that all participants have been diagnosed with a condition that falls into one of the above categories. The treatment of these diseases is usually carried out in specialized medical care. Follow-ups, on the other hand, can also be carried out in primary care, depending on the condition and stage of treatment.

The purpose of the study is to collect information on the disease being researched by examining patient records. Patient records refer to all information on the disease accumulated at the participant’s treatment unit and treatment details, including laboratory tests and results of medical imaging, as well as the treatments given and their outcomes. Participation in this study will not subject patients to any additional measures. Participation in this study or withdrawing from it will not in any way affect the treatment given to the patients. The basis for access to and recording patient data is provided in the written consent given by the participant.
After written consent to participate in the study has been given, the data collected from the participants' patient records are recorded in a special study database, which forms the Finnish Hematology Registry. The data are stored directly to the electronic database. Basic data collected about the participants are the same, but information specific to each disease is also collected, so the types of data gathered depend on the disease.

The data stored in the registry also includes personal identity codes. Personal identity codes can only be seen by the principal investigators and the staff of the treatment unit. The personal identity code authenticates the participant’s identity when their data is entered into the system.

In addition to patient records, data for the registry can also be added from the Population Register Center’s Population Information System, the Finnish Cancer Registry, Statistics Finland’s causes of death registry, Hospital Discharge Registers as well as parish records, provincial archives and local register offices according to the criteria required by them.

The Finnish Hematology Registry will be built upon the results of this study. The data stored in the registry can be accessed by authorized persons only. Research staff, in other words, doctors who treat and research hematological diseases and nurses who store the data, can browse the data stored in the registry that can be accessed without credentials (example: "Man, born 1954, chronic lymphocytic leukemia").

To protect the data contained in the registry, access to the database requires a username and a password. In addition, a log is kept on the use of the registry to enable identifying all the users. Data are entered and browsed via a secure connection. An up-to-date privacy statement and a GDPR-compliant privacy notice (General Data Protection Regulation) are available at your treatment unit and in electronic format at www.hematology.fi. The people who process personal data have been granted right of access to the registry.

This study registry is temporary and the collection of data will be terminated on 31 December 2030. The registry management group set up by the Board of FHR controls access to the registry and the analysis and reporting of data. Data collection in itself is important, but analyzing newly acquired information helps to assess the need to make operational changes. The registry serves as a data collection tool and it is useful as a broad source of information on various blood diseases. The FHR is responsible for the costs of the registry. Subjects of analysis may include, for example, what treatments have been used for a particular disease and what were the outcomes of such treatments, or whether individual differences in the patients’ diseases have an impact on the efficacy of the treatment. These analyses are made by individual researchers and research groups with the project-specific permission of the Board of FHR. The data are disclosed without any identifying details. If the analysis is performed by an external operator, they must demonstrate their compliance with the requirements of the General Data Protection Regulation (GDPR). The research groups carrying out analyses may include pharmaceutical industry operators.

**Advantages and disadvantages of the study**

The study gathers information that is currently lacking and will be helpful in developing treatments for blood diseases and bleeding disorders. As individual diseases, blood disorders are rare. The information accumulated about each person who participates in this study is valuable. The development of new treatments can be facilitated and accelerated through a better understanding of the national situation. The study will not necessarily benefit individual participants, but it will certainly have an impact on the future treatment of patients who have the same disorder or a disease of the blood in general.

Participation in the study is voluntary, and refusal will not affect any other treatments. Participation in the study can also be ended at any time without giving any reason. When a
participant leaves the study, storing data will stop and any identifying information about the participant will be deleted. For technical reasons, data already stored cannot be deleted if it has already been used in reports and analyses. The stored data correspond to the information in the patient documents. As a result, corrections made in accordance with the right of inspection are exported to the data in the registry where appropriate.

We are happy to answer any questions you may have about the study.

On behalf of the research group,

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Marjaana Säily, Adjunct Professor, Head of Department, Oulu University Hospital, Internal Medicine
The study: The Finnish Hematology Registry (FHR): Population-based follow-up study on the emergence, incidence, diagnostics, treatments and treatment outcomes of blood disorders and inherited bleeding disorders in Finland

CONSENT

I have read and understood the written description of the study mentioned above and I hereby voluntarily agree to participate in the study. I understand that taking part in this study that involves collecting data will not affect in any way the treatment or follow-up of my condition. I can withdraw from the study at any time and it will not affect in any way the treatment I receive later.

I require that the persons carrying out the study take the appropriate measures to ensure information security.

I hereby give my consent for

1) an authorized person to collect information from my patient records for the research database

2) my data to be browsed and saved in a secure browser-based environment

3) my data to be disclosed to analytical projects and international registries without my identifying information

Yes No

_______________________________________  _______________________________________
Date                                        Signature

_______________________________________  _______________________________________
Municipality of residence            Name in block letters

_______________________________________
Personal identity code

Legal guardian or representative on behalf of a person under the age of 15 or a person with a legal guardian:

_______________________________________  _______________________________________
Date                                        Signature

_______________________________________
Name in block letters

Consent received on:

_______________________________________  _______________________________________
Date                                        Signature and name in block letters

(This is the participant’s copy)
The study: The Finnish Hematology Registry (FHR): Population-based follow-up study on the emergence, incidence, diagnostics, treatments and treatment outcomes of blood disorders and inherited bleeding disorders in Finland

CONSENT

I have read and understood the written description of the study mentioned above and I hereby voluntarily agree to participate in the study. I understand that taking part in this study will not affect in any way the treatment I am given. I can withdraw from the study at any time and it will not affect in any way the treatment I receive later.

I require that the persons carrying out the study take the appropriate measures to ensure information security.

I hereby give my consent for

1) an authorized person to collect information from my patient records for the research database
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Yes ☐ No ☐

____________________________________
Date Signature

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Personal identity code

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____________________________________
Date Signature

____________________________________
Name in block letters

Consent received on:

____________________________________
Date Signature and name in block letters

(This copy is submitted to the registry for information purposes)